REMARKS

The Official Action of January 29, 2004, and the prior art relied upon therein have been carefully reviewed. Claims 1-21 are now in the application, of which claims 5-12 have not been rejected on the basis of any prior art, and applicants respectfully submit that all their claims define novel and unobvious subject matter warranting allowance thereof. Accordingly, applicants respectfully request favorable reconsideration and allowance.

Claims 1-20 have been rejected under the second paragraph of §112. This rejection is respectfully traversed.

Claim 1 has been objected to in various respects, so in deference to the examiners' views, claim 1 has been completely restructured so as to be re-presented in a more simplified manner. While the amended **form** of claim 1 is substantially different than the form of original claim 1, the subject matter covered is exactly the same. Therefore, the amendments are not "narrowing" amendments, i.e. the scope of the claims has not been reduced. No limitations have been added and none are intended, the amendments being entirely cosmetic.

As regards claims 2, 4, 6, 8-12, 15 and 16, the examiner's helpful suggestions have been adopted or

substantially adopted. For the record, applicants believe that the claims as originally drafted, considered in light of applicants' specification (fully consistent with the law), would not have been confusing to those skilled in the art, and therefore the claims in their original form are fully in accordance with §112. At **worst**, the language criticized in the claims might be considered objectionable, but **only** as to form, thus requiring no substantial amendments relating to patentability.

Applicants respectfully request withdrawal of the rejection based on the second paragraph of §112.

Claims 1-20 have been rejected under the first paragraph of §112. This rejection is respectfully traversed.

Examples 1-4 of the present application provide experiments in which mice and rabbits were used. It is clear from these examples that PTH(1-84) and the PTH derivative PTH(1-34) actually have a platelet increasing action. Thus, from the results of Examples 1-4, one skilled in the art may reasonably expect that such partial peptides and variants of PTH(1-84) and PTH(1-34) as the specification discloses, which were known at the time of the preset application was filed, e.g. PTH(1-38), PTH(35-84), PTH(1-64) and PTH(1-37), would also have a platelet increasing action. Please refer to the

paragraph (Result) appearing on page 14, lines 4-7, which states:

> From these results, one may well expect that even shorter partial peptides of PTH as well as partial peptides of intermediate sizes, for example, PTH(35-84) and PTH(1-64) would have similar actions.

Respectfully, the PTO has no evidence whatsoever which would cast doubt on the accuracy of applicants' specification, it being noted that the law is clear that what an applicant states in his specification is to be accepted by the PTO in the absence of evidence or good reasoning to the contrary.

Thus, it is demonstrated *in vitro* that PTH and PTH derivatives have a platelet increasing action. Even though the specification does not provide the results of working examples in which PTH or a PTH derivative was administered to a patient, the results of Examples 1-4 sufficiently support the utility of the claimed invention as "A method for increasing a platelet count in a patient in need thereof".

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1-4 and 13-20 have been rejected under §103 as obvious from Benigni et al (hereinafter simply "Benigni") in view of Stedmann's Medical Dictionary (hereinafter simply

"Stedmann's") and Krstenansky et al USP 5,589,452 (Krstenansky). This rejection is respectfully traversed.

The PTO asserts that, as concerns claims 1, 13 and 14, Benigni generally teaches that various concentrations of PTH and its derivative inhibit human platelet aggregation, and that to the extent that the platelet counts are concerned, use of PTH has been shown to clearly inhibit platelet aggregation in humans (pages 243-347). In addition, the PTO states that Stedmann's discloses that thrombocytopenia is "A condition in which there is an abnormally small number of platelets in the circulating blood". The PTO concludes that inhibiting platelet aggregation would be expected to result in an increase in the number of circulating platelets, and that those of ordinary skill in the art at the time the invention was made would have expected that the same agent (PTH) would be useful for treating patents having disorders due to having a small number of circulating blood platelets with the expectation of success.

However, Benigni merely teaches that PTH inhibits platelet aggregation and does not at all disclose an increase in the number of platelets. It is reported in Benigni that after platelet aggregation was induced by use of an aggregating agent, inhibition of platelet aggregation was observed by administration of PTH.

When platelets are aggregated, i.e. clumped together, they become relatively large, and of course the resultant aggregates are then smaller in number than the un-aggregated platelets. Such aggregates cannot be reasonably measured as single "platelets", but if such aggregates are individually measured as each being only one platelet, the number of platelets seemingly decreases. When aggregation is inhibited afterwards, i.e. the aggregates disassociates, the measurement or count of the resultant platelets will be restored to an ordinary (pre-aggregation) level. In light of the above, it is very likely to be misunderstood that the number of platelets seemingly increases by inhibiting platelet aggregation.

However, even if such a dis-aggregation occurs, the increase in the measurement is noting but a seeming increase. The actual number *per se* of platelets does not change.

When a person skilled in the art reads Benigni, he or she can expect only the following course of steps:

> *(1) administration of an aggregating agent resulting in platelet aggregation; (2) a seeming decrease in the number of platelets in measurement; (3) administration of PTH; (4) inhibition of platelet aggregation; (5) seeming restoration of the number of platelets upon measurement*

A person skilled in the art would consider that the change in number of platelets is an apparent change in terms of

measurement and that the actual number *per se* of platelets does not change, and that the number of platelets before administration of an aggregating agent does not increase after administration of PTH. Therefore, when one having ordinary skill in the art reads Benigni, he or she cannot reach the conception that the actual number *per se* of platelets increases by administration of PTH.

In contrast, according to the present invention, no coagulant is administered before administration of PTH and thus platelet aggregation is not induced. Therefore, it is evident that the action of increasing the number of platelets caused by the present invention leads to not merely a seeming increase in the number of platelets, but an actual increase in the number *per se* of platelets. Thus the action of PTH in the present invention is quite different from that taught by Benigni. This unexpected result that was found by the inventors of the present invention is neither disclosed nor suggested by Benigni.

Applicants do not see that Stedmann's adds anything to Benigni, or in any way detracts from applicants' remarks immediately above. The same points made above against Benigni apply equally to Benigni in view of Stedmann's.

Krstenansky is applied only against claims 15-20. Applicants choose at this time to reserve any arguments

against the proposed combination of Benigini in view of Krstenansky (or Benigni in view of Stedmann's and Krstenansky), at this time relying only on the fact that Krstenansky is not applicable to claim 1, and claims 15-20 incorporate the subject matter of claim 1. In other words, applicants at the present time rely on the patentability of claim 1 for all the claims which depend from and incorporate the subject matter of claim 1, even though in at least some cases the features added in the dependent portions of the dependent claims add additional patentable subject matter.

For the reasons set forth above, applicants respectfully request withdrawal of the rejection based on §103.

Applicants note for the record that claims 5-12 have not been rejected on the basis of any prior art. Applicants accordingly understand that claims 5-12 are deemed by the PTO to define novel and unobvious subject matter under §§102 and 103.

New claim 21, dependent on and incorporating claim 13, is patentable for the reasons pointed out above.

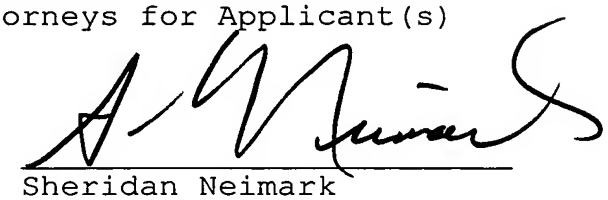
The prior art documents of record and not relied upon have been noted, along with the implication that such

documents are deemed by the PTO to be insufficiently pertinent to warrant their application against any of applicant s' claims.

Applicants respectfully request favorable reconsideration and allowance.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By 
Sheridan Neimark
Registration No. 20,520

SN:jaa
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
Document8